#7
9-5-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	**Confirmation No. 3505**
Kazuhiro OHKOUCHI et al.	:	Docket No. 2001_1692A
Serial No. 10/009,835	:	Group Art Unit 1615
Filed December 17, 2001	:	Examiner James M. Spear

QUICKLY DISINTEGRATING SOLID PREPARATIONS

RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is responsive to the Official Action dated March 26, 2003, the time for response being extended for two months in accordance with a petition for extension submitted concurrently.

Claims 1-32 are pending in this application. Claims 1-32 have been rejected.

Further and favorable reconsideration is respectfully requested.

I. At page 2 of the Official Action, claims 1-32 have been rejected under 35 U.S.C. § 102(b) as being clearly anticipated by WO 98/53798.

The Examiner states that claims 1-32 are anticipated in view of WO 98/53798, and points to example 1, claims 1-9, page 6, lines 7 and 35. The Examiner also states that additional disintegrates are shown on page 12, lines 17-26. In view of the following, this rejection is respectfully traversed.

Anticipation under 35 U.S.C. § 102(b), requires that each and every element of the claimed invention be disclosed in a single prior art reference.

WO 98/53798 is directed to a solid pharmaceutical preparation, including a pharmaceutically active ingredient, one or more water-soluble sugar alcohols, and a low-substituted hydroxypropylcellulose having a hydroxypropoxyl group content of 7.0 to 9.9 wt%, which exhibits excellent buccal disintegration and dissolution, and also appropriate strength.

The present invention is directed to a solid preparation that disintegrates quickly in the presence of saliva or a small amount of water in the oral cavity, and includes an active ingredient, a saccharide or sugar alcohol with a mean particle diameter of 30 microns to 300 microns, a disintegrating agent, and a cellulose compound.

The present solid preparation can be industrially produced using common industry practices, without requiring any special manufacturing techniques. The solid preparation is based on the present inventor's finding that a relatively coarse powder of a saccharide or a sugar alcohol, used together with a disintegrating agent and a cellulose compound, produces an effective, quickly disintegrating, solid preparation.

Regarding claims 1-18, WO 98/53798 does not teach or suggest a solid preparation including a saccharide or sugar alcohol having a mean particle diameter of 30 microns to 300 microns.

The reference, WO 98/53798, discloses that "as erythritol, ...a particle size of at most 50 mesh is used" (page 9, lines 8-11). 50 mesh is about 300μm. This disclosure merely indicates a general measure of a particle size of erythritol to be used and is by no means a definite upper limit of the particle size of erythritol to be used. Thus, this disclosure does not teach or suggest the specific upper limit of the mean particle size of a saccharide or a sugar alcohol of the present invention.

Moreover, the description "a particle size of at most 50 mesh" include particles having a mean particle size of less than 30 μm. Therefore, the particle sizes disclosed in the reference is clearly distinguished from the particle size of the present invention because the mean particle size of a saccharide or a sugar alcohol in the present invention must be 30 μm or more. In fact, there is no specific example of a pharmaceutical preparation using erythritol having a mean particle size of 30 μm or more in the reference.

Regarding present claims 19-32, these claims are directed to the combination of a fine powder of a saccharide or a sugar alcohol and a coarse powder of a saccharide or a sugar alcohol.

WO 98/53798 does not teach or suggest a solid preparation including a combination of a fine powder of a saccharide or a sugar alcohol and a coarse powder of a saccharide or a sugar alcohol, as required by present claims 19-32.

In view of the foregoing, it is submitted that WO 98/53798 does not teach each and every element of the claimed invention, as required for anticipation under 35 U.S.C. § 102(b). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

II. At page 2 of the Official Action, claims 1-13 and 18-32 have been rejected under 35 U.S.C. § 102(b) as being clearly anticipated by EP 0839526 A2.

The Examiner states that claims 1-13 and 18-32 are anticipated by EP 0839526 A2 and points to examples 1-6, claims 1-9, page 2, line 39 through page 3, line 15, in support of his position. In view of the following, this rejection is respectfully traversed.

EP 0839526 A2 is directed to a solid pharmaceutical preparation with fast buccal disintegration or dissolution, including a pharmaceutically active ingredient, erythritol, crystalline cellulose, and disintegrates.

None of the passages pointed out by the Examiner teach or suggest a solid preparation including a saccharide or sugar alcohol with a mean particle diameter of 30 microns to 300 microns, as required by the present claims 1-18.

Regarding the particle size of erythritol, the reference, EP 0839 526 A, discloses that "usually, erythritol products having a particle size capable through a 50 mesh sieve are used" (page 4, lines 23-24). This disclosure merely indicates a general measure of a particle size of erythritol to be used and is by no means a definite upper limit of the particle size of erythritol to be used. Thus, this disclosure does not teach or suggest the specific upper limit of the mean particle size of a saccharide or a sugar alcohol of the present invention.

Moreover, the description "erythritol products having a particle size capable through a 50 mesh sieve" and "a particle size of at most 50 mesh" include particles having a mean particle size of less than 30 μm. Therefore, the particle size disclosed in the references is clearly distinguished

from the particle size of the present invention because the mean particle size of a saccharide or a sugar alcohol in the present invention must be 30 μm or more. In fact, there is no specific example of a pharmaceutical preparation using erythritol having a mean particle size of 30 μm or more in the reference.

Regarding Examples 2, 3 and 4 of EP 0839526, there is no specific disclosure of the particle size of erythritol and mannitol in these Examples.

Further, none of the passages pointed out by the Examiner teach or suggest the combination of a fine powder of a saccharide or sugar alcohol with a coarse powder of a saccharide or a sugar alcohol, as required by claims 19-32.

Accordingly, it is submitted that EP 0839526 A2, does not teach each and every element of the claimed invention, as required for anticipation under 35 U.S.C. § 102(b). Thus, the Examiner is respectfully requested to withdraw this rejection.

In view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Such allowance is solicited.

If the Examiner has any questions regarding this response, the application in general, or has any suggestions for placing the application in condition for allowance, the Examiner is requested to call the undersigned at the number listed below.

Respectfully submitted,

Kazuhiro OHKOUCHI et al.

By: _____

Warren M. Cheek, Jr.
Registration No. 33,367
Attorney for Applicants

WMC/dlk
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
August 26, 2003